**Follow up to the European Parliament non-legislative resolution on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122, and genetically modified maize combining two, three or four of the single events MON 87427, MON 89034, 1507, MON 88017 and 59122 and repealing Decision 2011/366/EU**

**1. Resolution tabled pursuant to Rules 106(2) and (3) of the European Parliament's Rules of procedure by the Committee on the Environment, Public Health and Food Safety**

**2. Reference numbers:** 2018/2873 (RSP) / B8-0491/2018 / P8\_TA-PROV(2018)0417

**3. Date of adoption of the resolution:** 24 October 2018

**4. Subject:** Draft Commission Implementing Decision authorising genetically modified MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 maize

**5.** **Competent Parliamentary Committee:** Environment, Public Health and Food Safety (ENVI)

**6. Brief analysis/assessment of the resolution and requests made in it:**

The resolution calls for the withdrawal of the draft Commission Implementing Decision **(paragraph 4)**, based on the grounds that the draft implementing decision at stake exceeds the implementing powers provided for in Regulation (EC) No 1829/2003 **(paragraph 1)** and that it is not compatible with the aim of Regulation (EC) No 1829/2003 and the general principles of Regulation (EC) No 178/2002, i.e. protection of human life and health, animal health and welfare, the environment and consumer interests **(paragraph s 2 and 3)**. In addition, the resolution calls on the Commission to suspend any implementing decision regarding authorisation of genetically modified organisms until the authorisation procedure has been revised in such a way as to address the shortcomings of the current procedure, which has proven to be inadequate **(paragraph 5)**.

The resolution recalls the fact that the genetically modified maize, combining five events, is tolerant to glyphosate and glufosinate herbicides **(recitals G and H)**. The resolution recalls that glufosinate is classified as toxic to reproduction and its approval for use in the Union expired on 31 July 2018 **(recital G)**, states that questions concerning the carcinogenicity of glyphosate remain **(recital H)** and states that the authorisation decision will increase demand for cultivation of this maize in third countries with a corresponding increase in use of those herbicides **(recital I**). The resolution also recalls that the genetically modified maize is resistant to insects (**recital J**) and mentions that the Bt proteins (Bacillus thuringiensis proteins) may have toxic effects (**recital K**) and that there are concerns about possible evolution of resistances to Bt proteins, possibly leading to altered pest control practices in third countries (**recital L)**. The resolution recalls that no experimental data were provided by the applicant for fourteen sub-combinations of this maize **(recital E)**, and that no toxicology testing nor animal studies with food/ feed derived from the genetically modified maize or its sub-combinations were provided **(recitals F and M)**. Finally, the resolution mentions the fact that one sub-combination previously authorised has been incorporated in the scope of the present decision at the applicant’s request, and questions the legitimacy of such an approach (**recital C**).

The resolution recalls the voting results on the draft implementing decision in the Standing Committee **(recital P)**. Furthermore, the resolution recalls that the return of the draft authorising decisions to the Commission for final decision, after not being supported by the Standing Committee on the Food Chain and Animal Health, has become the norm for decision-making on genetically modified food and feed authorisations and it is not democratic **(recital Q)**. Finally, the resolution recalls the rejection by the Parliament of the Commission's legislative proposal of 22 April 2015 amending Regulation (EC) No 1829/2003, and the Parliament's call on the Commission to withdraw that proposal and submit a new one **(recital R)**.

**7. Response to the requests in the resolution and overview of the action taken, or intended to be taken, by the Commission:**

The Commission would like to explain that the draft implementing decision at stake authorises the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122, and genetically modified maize combining two, three or four of the single events MON 87427, MON 89034, 1507, MON 88017 and 59122, but not the cultivation of this maize.

With respect to **paragraphs 1 to 5** of the resolution, the Commission would like to point out that the draft implementing decision has been processed in line with the procedural steps set out in Regulation (EU) 182/2011 on comitology and Regulation (EC) No 1829/2003 on genetically modified (GM) food and feed, as illustrated below:

* Application for the authorisation of GM maize maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 for food and feed uses in the European Union was submitted by Monsanto Company on 26 November 2013.
* The European Food Safety Authority **(**EFSA) performed a comprehensive risk assessment of the product and published on 5 September 2017 a favourable opinion concluding that GM maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122 is as safe and nutritious as its non-genetically modified comparator and other tested non-GM commercial varieties.
* In its opinion, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.
* The public had the opportunity to comment on the EFSA opinion but no comments were received during this public consultation.
* The draft implementing decision was voted on 11 September 2018 in the Standing Committee with no qualified majority against or in favour.
* In accordance with the rules set in Regulation (EU) 182/2011 on comitology, the Commission proposed the draft implementing decision to the Appeal Committee of 22 October 2018, where no qualified majority against or in favour was obtained either.

The Commission, therefore, considers that by adopting an implementing decision which fully complies with the procedural steps set out by the co-legislators in the GMO legislation it does not exceed its implementing powers. Consequently, there are no reasons to withdraw the draft implementing decision for authorisation of the GM maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122. Furthermore, following the submission of an application and the respective opinion of EFSA, Article 7(3) and Article 19(3) of Regulation (EC) No 1829/2003 oblige the Commission to act, namely to adopt a final decision on the application.

At the meeting of the Environment, Public Health and Food Safety Committee of the European Parliament on 18 October 2018, the Commission extensively explained the state of play of the authorisation procedure and why it had not exceeded its implementing powers.

With respect to the **other provisions of the resolution**, the Commission considers that they fall outside the remit of the right of scrutiny, which is limited to the question of whether the draft implementing act exceeds the implementing powers provided for in the basic act. The Commission is not required to justify the draft implementing act as regards these points. Nevertheless, the Commission has carefully considered the positions expressed by the European Parliament and would like to make the following comments:

* With respect to the specific concerns raised in **recitals G and H** of the resolution, the Commission would like to point out that the risk assessment in the context of an application for food and feed uses of an herbicide-tolerant crop is focused on the potential impact of the genetic modification on human and animal health and on the environment. The risk assessment and authorisation of herbicides is subject to the procedures set out in Regulation (EC) No 1107/2009, and the maximum residue levels (MRLs) are set under Regulation (EC) No 396/2005.
* With respect to the comments in **recital C**, the Commission took into consideration the request of the applicant and the fact that EFSA had not identified any safety concerns related to that specific sub-combination, the Commission considered appropriate to include this sub-combination in the scope of the implementing decision.
* With regards to the comments in **recital R** on the Commission legislative proposal for a regulation amending Regulation (EC) No 1829/2003 as regards the possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory, the Commission would like to recall that it regrets the decision of the European Parliament of 28 October 2015 to reject the proposal. The Commission maintains its original proposal, which, if adopted, would enable the Member States to address at national level considerations which are not covered by the European Union decision making process.
* Furthermore, with regards to the lacking support of the Members States for any authorising decision of GMOs for food and feed uses **(recital P)** the Commission submitted a proposal to the Council and the European Parliament on 14 February 2017 to change the voting rules at the Appeal Committee, which, if adopted by co-legislators, would increase transparency and accountability in GMO decision-making process.
* In conclusion, the Commission would like to stress that as for any legislative procedure submitted under the ordinary legislative procedure, the rules in place continue to apply during the negotiations between the co-legislators and until a final agreement is found. Consequently, the Commission has to continue processing the applications for GM food and feed.